Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations.

OMB No. 0915-0327 – Revision

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted as Section 340B of the Public Health Service Act (PHS Act; ''Limitation on Prices of Drugs Purchased by Covered Entities''), provides that the Secretary of Health and Human Services will enter into a Pharmaceutical Pricing Agreement (PPA) with each manufacturer of covered outpatient drugs in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price decreased by a rebate percentage. Under this PPA, a manufacturer agrees not to charge a price for covered outpatient drugs that exceeds an amount determined under a statutory formula (ceiling price). A manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed in the 340B Program database if such drug is made available to any other purchaser at any price. The manufacturer shall rely on the information in the 340B database to determine if the covered entity is participating in the 340B Program or for any notifications of changes to eligibility that may occur within a quarter. By signing the PPA, the manufacturer agrees to comply with all applicable statutory and regulatory requirements. In response to comments submitted during the

first public review of this ICR, the language has been revised in this notice and in the draft instruments in order to align with the applicable statutory language regarding the obligation to sign the PPA, the circumstances under which participating manufacturers must offer covered outpatient drugs to covered entities, and the description of the ceiling price data required to be provided.

The purpose of this revision is to include an addendum to the PPA to incorporate the administrative requirement for manufacturer integrity provisions directly addressed in the Affordable Care Act.

Need and Proposed Use of the Information: HRSA is proposing revisions to the current PPA to include an addendum in response to manufacturer integrity provisions implemented in the Affordable Care Act. Section 7102(b) of the Affordable Care Act amends section 340B(a)(1) of the Public Health Service Act (PHSA) to add two new requirements for inclusion in the PPA with manufacturers of covered outpatient drugs:

I. "Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug . . ." and

II. "…shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

These requirements shall be included in the PPA addendum to be signed by manufacturers

participating in the 340B Program to ensure that the provisions of the 340B statute requiring inclusion in the PPA are satisfied. The execution of the addendum by manufacturers will fulfill the administrative requirement of the statute that these provisions be included in the PPA. The burden imposed on manufacturers by the proposed requirement of the PPA is minimal because the addendum does not impose requirements beyond review and a signature by the manufacturer.

Likely Respondents: Drug Manufacturers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Hours per Respondent	Total Burden Hours
Hospital Enrollment, Additions & Recertifications					
340B Program Registrations & Certifications for	194	1	194	2	388

Hospitals					
Certifications to Enroll Hospital Outpatient Facilities	697	8	5576	0.5	2788
Hospital Annual Recertifications	2134	6	12804	0.25	3201
Registrations and Recertifications for Entities Other Than Hospitals					
340B Registrations for Community Health Centers	427	3	1281	1	1281
340B Registrations for STD/TB Clinics	647	1	647	1	647
340B Registrations for Various Other Eligible Entity Types	405	1	405	1	405
Community Health Center Annual Recertifications	1204	5	6020	0.25	1505
STD & TB Annual Recertifications	3123	1	3123	0.25	780.75
Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics	4899	1	4899	0.25	1224.75
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	1758	5	8790	1	8790
Other Information Collections					
Submission of Administrative Changes for any Covered Entity	9396	1	9396	0.5	4698
Submission of Administrative Changes for any Manufacturer	350	1	350	0.5	175
Manufacturer Data Required to Verify 340B Ceiling Price Calculations	600	4	2400	0.5	1200

Pharmaceutical Pricing Agreement	200	1	200	1	200
Pharmaceutical Pricing Agreement (PPA) Addendum	620	1	620	0.5	310
Total	**26,654**		**56,705**		**27593.5**

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter

Director, Division of the Executive Secretariat

[FR Doc. 2016-08110 Filed: 4/7/2016 8:45 am; Publication Date: 4/8/2016]